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10/663,010	09/15/2003	Tim Clarot	33205.0800	1757

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,010	CLAROT ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 and 13-40 are pending. Applicant has cancelled claim 12. Receipt and consideration of Applicants' claim amendments and remarks/arguments, submitted on May 3, 2006 is acknowledged. The previous office action mailed on July 24, 2006 is vacated so the Examiner may clarify which claims are rejected under which statute, and Applicant is able to respond accordingly. The time for reply is reset to begin from the mailing date of the instant office action.

Moot Rejections/objections

All rejections and/or objections of claim 12 cited in the office action mailed on December 1, 2005 **are moot**, because said claim has been cancelled.

Specification

The objections to the disclosure, claim 1, and claim 11 because of informalities, as described on page 2 of the previous office action **are withdrawn**, per Applicants' amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13-32, and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "reducing a duration of symptoms associated with a cold" in amended claim 11 is new matter, because the instant specification lacks support for said phrase. **The amended upper limit for the amount of carrier claimed in claims 24 and 30-31 constitutes new matter**. The specification does not contain said range. The range recited in the instant specification is about 90 to about 99.999 weight percent. See paragraph [0026]. Claims 32 and 34 claim compositions further comprising a "moisturizing agent," however, nowhere in the specification is the term "moisturizing agent" found nor are compounds identified as being moisturizers, humectants, emollients. Therefore, new **claims 32 and 34 constitute new matter**. It is noted that Applicant did not indicate the location for the support within the instant specification for any of the claim amendments.

The remaining claims are rejected for depending from a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-39 are indefinite because it is unclear what is the intended meaning of the term "system" in said claims. A system is normally interpreted to read on a method. It is noted that the claims could also be interpreted as reading on a kit. The use of the term "system" in the

context of claims 36-39 is not defined or explained in the specification. Appropriate clarification is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 2, 11-15, and 27-29 under 35 U.S.C. 102(a) as being anticipated by Davidson et al. (U.S. Patent No. 6,365,624) **is withdrawn**, per Applicants' amendments.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 40 (new claim) is rejected under 35 U.S.C. 102(e) as being anticipated by Haslwanter et al. (U.S. Patent No. 6,316,483).

Applicant claims a composition consisting essentially of (i) about 0.045 wt % to about 0.055 % w/w oxymetazoline; (ii) about 0.00001 to about 5.0 % w/w permeation enhancer; (iii) about 0 to about 1 .0 % w/w aromatic substance; (iv) about 0.0001 to about 1.0 % w/w preservative; (v) about 0.000001 to about 5.0 % w/w thickener; (vi) about 90 to about 99 % w/w water; (vii) about 0.00001 to about 1.0 % w/w emulsion agent; and (viii) about 0.0002 to about 6.0 % w/w buffer.

Haslwanter discloses in Example 2, an aqueous nasal spray composition:

INGREDIENTS	% Wt/Vol
Water	QS
Disodium EDTA	0.0200
Sodium Phosphate Dibasic	0.0975
Sodium Phosphate Monobasic	0.5525
PVP K-90	0.2500
PVP K-30	1.0000
PEG 1450	2.5000
Benzyl Alcohol	0.2500
Benzalkonium Chloride (17% solution)	0.0200
Oxymetazoline Hydrochloride	0.0500

Disodium EDTA, benzyl alcohol, benzalkonium chloride, PEG-1450, PVP K-90/PVP K-30, and sodium phosphate dibasic/sodium phosphate monobasic are a permeation enhancer, aromatic substance, preservative, thickener, emulsion agent, and buffer, respectively. The amount of water in the Haslwanter composition in Example 2 is approximately 95% w/v, which overlaps with the amount required by the Applicants' claimed composition.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections of (1) claims 3-10 and 16-26 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) **is maintained**, for the reasons of record as described in the office action mailed on December 1, 2005 and reiterated herein below. Claims 1, 2, 11, 13-15, and 27-29, previously rejected under 35 U.S.C. 102(a) as being anticipated by Davidson, are appended to this rejection. New claims 33-35 are also appended to this rejection for the reasons of record. In summary, **claims 1-11, 13-29, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable**

over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269).

The rejection of claims 30-31 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) as previously applied to claims 3-10 and 16-26 above, and further in view of Pier (U.S. Patent No. 6,245,735) **is maintained**, for the reasons of record as described in the office action mailed on December 1, 2005 and reiterated herein below. As set forth above, claims 1, 2, 11, 13-15, 27-29, and 33-34 are rejected as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269). In summary, **claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) as applied to claims 1-11, 13-29, and 33-34 above, and further in view of Pier (U.S. Patent No. 6,245,735)**, for the reasons of record.

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) as applied to claims 1-11, 13-31 above, and further in view of Seidel et al. (US 2001/0053775) or MacRae et al. (US 2002/0046751).

Applicant Claims

Applicant claims a system comprising (1) a composition having (a) about 75 to about 99.999% w/w carrier, (b) about 0.000001 to about 10 % w/w, an active substance selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, xylometaxoline hydrochloride, wherein the composition has a viscosity greater than about 2,500 centipoise and less than about 40,000 centipoise, and (c) a thickener selected from the group consisting of glycerin, carrageenan, sugar, guar gum, methylcellulose, hydroxyethylcellulose, carbohydrate thickeners, and (2) a nasal applicator containing said composition.

"System" is interpreted as referring to a kit, wherein inhalers containing a composition are considered a kit. The intended use of the claimed product was given no weight in examination.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Davidson and Haslwanter have been set forth on pages 7-10 of the previous office action. In Examples 1 and 2, Seidel teaches nasal compositions, shown below:

EXAMPLE 1

[0039] Nasal drops containing 0.1% (m/V) of Xylometazoline hydrochloride

Xylometazoline hydrochloride	0.10%
Sodium dihydrogen phosphate dihydrate	0.50%
Disodium phosphate dodecahydrate	0.17%
Disodium edetate	0.05%
Benzalkonium chloride	0.01%
Sorbitol (70% in water, non-crystallizing)	2.00%
Hydroxypropyl methyl cellulose (viscosity 4000 mPa·s)	0.50%
Sodium chloride	0.40%
Purified water	97.17%
	100.90% (m/V)

EXAMPLE 2

[0043] Nasal spray containing 0.05% (m/V) of Oxymetazoline hydrochloride

[0044] The composition and manufacturing method is the same as in Example 1, with the exception that 0.05% oxymetazoline hydrochloride is used (instead of 0.10% xylometazoline hydrochloride) and the content of purified water is 97.22% (instead of 97.17%). The solution is filled into a squeeze bottle fitted with a nosepiece and a protection cap.

A squeeze bottle filled with a nasal composition and fitted with a nosepiece (Seidel, Example 2) reads on a nasal applicator containing a nasal composition.

MacRae teaches **a nasal inhaler for introducing a substance to a nasal cavity** of a user (title, abstract, Figures 1-73, claims 1, 33, and the product produced by the method of claims 39-43).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Davidson and Haslwanter lack the express teaching of a composition contained within a nasal applicator (i.e. nasal inhaler or spray device). These deficiencies are cured by the teachings of Seidel or MacRae.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Davidson and Haslwanter to include their invented

nasal decongestant compositions within a nasal inhalation device (Seidel or MacRae). A skilled artisan would have been motivated to put the compositions resulting from the combination of Davidson and Haslwanter within a nasal inhalation device, such as that taught by Seidel or MacRae, because said devices are obviously intended to contain and administration nasal compositions. A skilled artisan would have had a reasonable expectation of success upon combining the teachings of Davidson and Haslwanter with the teachings of Seidel or MacRae, because nasal inhalation devices are designed to contain and deliver nasal compositions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claim 29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No.

10/664,839 (copending '839) **is maintained** for the reasons of record on page 12 of the previous office action.

The provisional rejection of claims 1 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-29 and 34 of copending Application No. 11/028,991 (copending '991) in view of Seifert (USPN 5,100,028; USPN '028) **is maintained** for the reasons of record on pages 12-13 of the previous office action.

Response to Arguments

Applicant's arguments with respect to claims 1-2 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments filed May 3, 2006 have been fully considered but they are not persuasive. Applicant traverses the rejections of (1) claims 3-10 and 16-26 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) as applied to claims 1, 2, 11-15, and 27-29 above, and further in view of Haslwanter et al. (U.S. Patent No. 5,854,269); and (2) claims 30-31 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) as applied to claims 3-10 and 16-16 above, and further in view of Pier (U.S. Patent No. 6,245,735).

Regarding the first rejection under 35 U.S.C. §103(a), Applicant contends that (a) there is no motivation to combine the teachings of Davidson and Haslwanter and (b) the prior art fails to teach or suggest compositions comprising about 0.001 to about 5.0 % w/w decongestant selected from "oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine

hydrochloride, xylometaxoline hydrochloride, wherein the composition has viscosity greater than about 2,500 centipoise. The Examiner respectfully disagrees.

Both Davidson and Haslwanter teach compositions comprising a combination of decongestants: (1) zinc gluconate and menthol (Davidson) or (2) oxymetazoline or pharmaceutically acceptable salt thereof and menthol (Haslwanter) for application to the nasal membrane (i.e. the prior art teaches nasal compositions). A skilled artisan would have been motivated to look to both Davidson and Haslwanter for guidance as to the required properties of a nasal decongestant composition (e.g. a viscosity greater than about 5,000 centipoise as taught by Davidson) as well as to decongestants that one could employ in such a composition (e.g. zinc gluconate (Davidson), menthol (Davidson & Haslwanter), and oxymetazoline (Haslwanter)). A skilled artisan would also have been motivated to combine the prior art references, because both utilize menthol, which is desirable, due to its ability to mask the odor of aromatic alcohols (Haslwanter, col. 1, lines 57-59). It is noted that the term "oxymetazoline or pharmaceutically acceptable salt thereof (e.g. oxymetazoline hydrochloride in Example 6)" reads on oxymetazoline hydrochloride; Haslwanter teaches oxymetazoline or pharmaceutically acceptable salt thereof in the range of about 0.01 % to about 0.1 % by weight/volume (w/v), which overlaps with the range claimed by Applicant (See Example 6); and hydrochloride salts are well known pharmaceutically acceptable salts of oxymetazoline and other active agents (see for example, (a) Block et al, U.S. Patent No. 6,090,403 [col. 2, line 61 through col. 3, line 5] or (b)Bastin, R. J. et al. "Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities," *Organic Process Research & Development*, **2000**, *4*, 427-435). A person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success upon

combination of the teachings of Haslwanter and Davidson, because both references teach nasal compositions comprising menthol.

Regarding the rejection of record under 35 U.S.C. §103(a) concerning claims 30-31 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) and further in view of Pier (U.S. Patent No. 6,245,735), Applicant traverses for the reasons described above and contends that there is no motivation to combine Pier with Davidson and Haslwanter. The Examiner respectfully disagrees. Pier teaches that his composition, comprising covalently conjugated polysaccharide liposomes, may contain virtually any bioactive agent within the liposome, including nasal decongestants (column 3, lines 30-38 and column 9, lines 15-18 and 65).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-11 and 13-40 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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